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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/769,961	02/02/2004	Hans-Dietrich Polaschegg	POLA-01	9120

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EXAMINER
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ROGERS, JAMES WILLIAM

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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05/14/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/769,961	<b>Applicant(s)</b> POLASCHEGG, HANS-DIETRICH	
	<b>Examiner</b> JAMES W. ROGERS	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-7 and 9-20 is/are pending in the application.
- 4a) Of the above claim(s) 9,10,16-18 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-7,11-15 and 19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04/01/2008</u>  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicants amendments to the claims and the specification filed 03/17/2008 have been entered. Any rejection/objection from the previous office action filed 09/12/2007 not addressed in the action below has been withdrawn.

### ***Election/Restrictions***

Newly submitted claims 16-18 and 20 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claim 16 and 20 are drawn to a system that comprises a hemodialysis catheter and a catheter lock composition, the composition claims of group I that was elected without traverse in the response to the election/restriction requirement filed 07/19/2007 was not drawn to a system that requires a hemodialysis catheter thus the new claims are independent of the elected invention. Also method claim 17 further requires the use of a hemodialysis catheter and deploying it within the patient, this new claim is distinct from elected group I because group I is a composition and as such does not require the use of a hemodialysis catheter since the intended use is not limiting for the composition. Similarly claim 18 is drawn to a method of preventing microbial colonization of a lumen of a catheter however since the intended use of a composition is not limiting for the composition claims of group I the new claims are independent of the elected invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 16-18 and 20 are withdrawn from

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consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1,3-7,11-15 and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These new rejections were necessitated by applicant's amendments to the claims. Specifically within claim 1 the examiner could not find support within the specification for new step (i) which states the gel is **easy flow under the shear forces imparted by a syringe such that the composition may be instilled into, and withdrawn from, a hemodialysis catheter using such a conventional medical syringe**. Furthermore within claim 1 the examiner could not find written support within the specification as originally filed for new step (iii) that states that **the composition remains in the lumen substantially without leakage**. The examiner could not find support within the specification for the above new limitations within claim 1 nor have applicants met their burden to show support for the above new limitations within their remarks. Also within new claim 19 the examiner could not find support within the specification that the gel is a colloidal suspension. The only

description for a colloid within the specification states that the colloidal substance or gel could have properties similar to a colloidal dispersion; however it does not state that the gel is a colloidal suspension. Applicants also have not met their burden to show support for the new limitation within claim 19.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1,3-5,11,13-15 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Luissi et al. (US 4,587,284), for the reasons set forth in the previous office action filed 09/12/2007. A new rejection of the claims was necessitated by amendment.

Regarding new claim 11, Luissi specifically describes the use of natural polymers such as a gelable polysaccharide, and/or protein or polypeptide within the hydrogel. See abstract and claims. Regarding new claims 13-15, Luissi specifically describes the use of polyacrylic acid interspersed with the above natural polymers within the hydrogel. See abstract and claims. Regarding new claim 19, generally gels are colloids which are immobilized by surface tension between the macromolecular fibers and the gelling

agent, thus it is the position of the examiner that any gel can be considered as a colloidal suspension since the fibers are suspended and the gel is a colloid.

Claims 1,3-4,6,13-15 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Marchant et al. (US 6,297,337 B1), for the reasons set forth in the previous office action filed 09/12/2007. A new rejection of the claims was necessitated by amendment.

Regarding new claims 13-15 Marchant teaches the use of polyacrylic acid. See claims. Regarding new claim 19, generally gels are colloids which are immobilized by surface tension between the macromolecular fibers and the gelling agent, thus it is the position of the examiner that any gel can be considered as a colloidal suspension since the fibers are suspended and the gel is a colloid.

Claims 1,3-5,11-15 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Wokalek et al. (US 4,905,700), for the reasons set forth in the previous office action filed 09/12/2007. A new rejection of the claims was necessitated by amendment.

Regarding new claims 11-12 Wokalek specifically teaches the use of alginates within the hydrogel. See col 1 lin 54-57. Regarding new claims 13-15 Wokalek specifically teaches the use of polyacrylic acid. See col 1 lin 62-64. Regarding new claim 19, generally gels are colloids which are immobilized by surface tension between the macromolecular fibers and the gelling agent, thus it is the position of the examiner

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that any gel can be considered as a colloidal suspension since the fibers are suspended and the gel is a colloid.

Claims 1,3,7,11-15 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Young et al. (US 2003/0180347 A1), for the reasons set forth in the previous office action filed 09/12/2007. A new rejection of the claims was necessitated by amendment.

Regarding new claims 11-12 Young specifically teaches the use of collagen within the hydrogel. See [0031] and claims. Regarding new claims 13-15 Young specifically teaches the use of polyacrylic acid and carboxymethyl cellulose. See abstract, [0027] and claims. Regarding new claim 19, generally gels are colloids which are immobilized by surface tension between the macromolecular fibers and the gelling agent, thus it is the position of the examiner that any gel can be considered as a colloidal suspension since the fibers are suspended and the gel is a colloid.

Claims 1,3-5 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by PFIRRMANN et al. (WO 94/03174), for the reasons set forth in the previous office action filed 09/12/2007.

Regarding new claim 19, generally gels are colloids which are immobilized by surface tension between the macromolecular fibers and the gelling agent, thus it is the position of the examiner that any gel can be considered as a colloidal suspension since the fibers are suspended and the gel is a colloid.

### ***Response to Arguments***

Applicant's arguments filed 03/17/2008 have been fully considered but they are not persuasive.

Applicants assert that none of the cited references relates to a catheter lock and thus none of the compositions are similar to their claimed invention.

The examiner respectfully disagrees with the above assertion. The intended use type of limitations within steps (i)-(iii) of claim 1 are considered met by the prior art because the compositions are within applicants claimed scope thus they will inherently be able to perform the same intended use even if this feature is not disclosed within the references. Applicants have not amended their claims in such a way as to preclude the prior art references since applicants composition does not limit the ingredients or the amounts of those ingredients so that the prior art does not anticipate their claims. The subject matter of a properly construed claim is defined by the terms that limit its scope. It is this subject matter that must be examined. As a general matter, the grammar and intended meaning of terms used in a claim will dictate whether the language limits the claim scope. Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation

Applicants assert that their composition requires a thixotropic gel with an antimicrobial contained within and Luissi, Wokalek, Pfirrmann and Young all fail to disclose a thixotropic gel.



The relevance of this assertion is unclear. As already stated above since the references all teach a composition within applicants claimed scope it is assumed that the same composition will have the same properties. It appears as though applicants may be attempting to claim a new property of an old composition. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case or either anticipation or obviousness has been established, Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Applicants further assert that while Marchant does describe a thixotropic gel the reference does not disclose the use of the composition as a catheter lock. Applicants further note that Marchant is drawn to a bioadhesive polymer composition which would make it unsuitable as a composition in a hemodialysis catheter.

Once again applicant's claims do not preclude the composition of Marchant since as amended applicant's claimed scope overlaps the composition described by Marchant. The subject matter of a properly construed claim is defined by the terms that limit its scope. It is this subject matter that must be examined. As a general matter, the grammar and intended meaning of terms used in a claim will dictate whether the language limits the claim scope. Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation

### ***Conclusion***

No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP §706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

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information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618